

IHCP *bulletin*

INDIANA HEALTH COVERAGE PROGRAMS BT2024126 AUGUST 8, 2024

IHCP announces expanded coverage of biomarker testing

In accordance with *Senate Enrolled Act 273 (SEA 273)*, beginning **July 1, 2024**, the Indiana Health Coverage Programs (IHCP) will expand coverage for biomarker testing when certain conditions are met. As used in this policy, *biomarker testing* means the analysis of a patient's tissue, blood or other biospecimen for the presence of a biomarker. The IHCP coverage information in Table 1 is effective for dates of service (DOS) on or after **July 1, 2024**.



Biomarker testing may be medically necessary and a covered benefit for the purposes of diagnosis, testing, treatment, appropriate management or ongoing monitoring of a member's disease or condition when biomarker testing is supported by medical evidence, including:

- Labeled indications for a test approved or cleared by the U.S. Food and Drug Administration (FDA)
- Indicated tests for a drug approved by the FDA
- A warning or precaution on the label of a drug approved by the FDA (where a drug may not be suitable for patients with a specific genetic makeup)
- A national coverage determination (NCD) of the Centers for Medicare & Medicaid Services (CMS)
- A local coverage determination (LCD) of a Medicare administrative contractor
- Nationally recognized clinical practice guidelines or consensus statements

For the purpose of this coverage policy, *consensus* means a statement that is:

- Issued by an independent, multidisciplinary panel of experts that:
 - Uses a transparent methodology and reporting structure
 - Has a conflict-of-interest policy
- Aimed at specific clinical circumstances
- Based on the best available evidence
- Developed for the purpose of optimizing the outcomes of clinical care

For the purpose of this coverage policy, *nationally recognized clinical practice guidelines* means evidence-based clinical practice guidelines that:

- Are developed by an independent organization or medical professional society that:
 - Uses a transparent methodology and reporting structure
 - Has a conflict-of-interest policy
- Establishes standards of care informed by:
 - A systematic review of evidence
 - An assessment of the benefits and risks of alternative care options
 - Recommendations intended to optimize patient care

The services provided must be provided in a manner that limits disruptions in care, including the need for multiple biopsies of biospecimen samples.

This policy does not include coverage of biomarker testing for screening purposes, unless there is evidence of a high risk to the member and a screening may be appropriate to inform the plan of care. Tests that are not FDA approved or supported by nationally recognized clinical practice guidelines will not be considered a covered benefit. Tests that do not have a Medicare fee schedule will not be considered a covered benefit.

Table 1 – Newly covered biomarker testing codes, effective for DOS on or after July 1, 2024

Procedure code	Description	Program coverage	PA required
81105	Hpa-1 genotyping	Covered	No
81106	Hpa-2 genotyping	Covered	No
81107	Hpa-3 genotyping	Covered	No
81108	Hpa-4 genotyping	Covered	No
81109	Hpa-5 genotyping	Covered	No
81110	Hpa-6 genotyping	Covered	No
81111	Hpa-9 genotyping	Covered	No
81112	Hpa-15 genotyping	Covered	No
81170	Abl1 gene	Covered	Yes
81178	Atxn1 gene detc abnor allele	Covered	No
81179	Atxn2 gene detc abnor allele	Covered	No
81180	Atxn3 gene detc abnor allele	Covered	No
81181	Atxn7 gene detc abnor allele	Covered	No
81182	Atxn8os gen detc abnor allel	Covered	No
81183	Atxn10 gene detc abnor allel	Covered	No
81184	Cacna1a gen detc abnor allel	Covered	No

Table 1 – Newly covered biomarker testing codes, effective for DOS on or after July 1, 2024 (Continued)

Procedure code	Description	Program coverage	PA required
81185	Cacna1a gene full gene seq	Covered	Yes
81186	Cacna1a gen known famil vrnt	Covered	No
81191	Ntrk1 translocation analysis	Covered	Yes
81192	Ntrk2 translocation analysis	Covered	Yes
81193	Ntrk3 translocation analysis	Covered	Yes
81194	Ntrk translocation analysis	Covered	Yes
81205	Bckdhb gene	Covered	No
81209	Blm gene	Covered	No
81210	Braf gene	Covered	No
81221	Cftr gene known fam variants	Covered	No
81222	Cftr gene dup/delet variants	Covered	Yes
81223	Cftr gene full sequence	Covered	Yes
81224	Cftr gene intron poly t	Covered	No
81225	Cyp2c19 gene com variants	Covered	Yes
81226	Cyp2d6 gene com variants	Covered	Yes
81227	Cyp2c9 gene com variants	Covered	Yes
81240	F2 gene	Covered	No
81241	F5 gene	Covered	No
81242	Fancc gene	Covered	No
81247	G6pd gene alys cmn variant	Covered	No
81248	G6pd known familial variant	Covered	Yes
81249	G6pd full gene sequence	Covered	Yes
81256	Hfe gene	Covered	No
81260	lkbkap gene	Covered	No
81271	Htt gene detc abnor alleles	Covered	No
81272	Kit gene targeted seq analys	Covered	Yes
81273	Kit gene analys d816 variant	Covered	No
81274	Htt gene charac alleles	Covered	Yes
81275	Kras gene variants exon 2	Covered	No
81284	Fxn gene detc abnor alleles	Covered	No

Table 1 – Newly covered biomarker testing codes, effective for DOS on or after July 1, 2024 (Continued)

Procedure code	Description	Program coverage	PA required
81285	Fxn gene charac alleles	Covered	Yes
81286	Fxn gene full gene sequence	Covered	Yes
81289	Fxn gene known famil variant	Covered	No
81290	Mcoln1 gene	Covered	No
81314	Pdgfra gene	Covered	Yes
81324	Pmp22 gene dup/delet	Covered	Yes
81325	Pmp22 gene full sequence	Covered	Yes
81326	Pmp22 gene known fam variant	Covered	No
81331	Snrpn/ube3a gene	Covered	No
81332	Serpina1 gene	Covered	No
81336	Smn1 gene full gene sequence	Covered	Yes
81337	Smn1 gen nown famil seq vrnt	Covered	No
81339	Mpl gene seq alys exon 10	Covered	No
81340	Trb@ gene rearrange amplify	Covered	Yes
81341	Trb@ gene rearrange dirprobe	Covered	No
81342	Trg gene rearrangement anal	Covered	Yes
81343	Ppp2r2b gen detc abnor allele	Covered	No
81344	Tbp gene detc abnor alleles	Covered	No
81349	Cytog alys chrml abnr lw-ps	Covered	Yes
81351	Tp53 gene full gene sequence	Covered	Yes
81352	Tp53 gene trgt sequence alys	Covered	Yes
81353	Tp53 gene known famil vrnt	Covered	Yes
81355	Vkorc1 gene	Covered	No
81362	Hbb gene known fam variant	Covered	Yes
81363	Hbb gene dup/del variants	Covered	Yes
81373	Hla i typing 1 locus lr	Covered	No
81374	Hla i typing 1 antigen lr	Covered	No
81376	Hla ii typing 1 locus lr	Covered	No
81380	Hla i typing 1 locus hr	Covered	No
81381	Hla i typing 1 allele hr	Covered	No

Table 1 – Newly covered biomarker testing codes, effective for DOS on or after July 1, 2024 (Continued)

Procedure code	Description	Program coverage	PA required
81382	Hla ii typing 1 loc hr	Covered	No
81383	Hla ii typing 1 allele hr	Covered	No
81400	Mopath procedure level 1	Covered	No
81401	Mopath procedure level 2	Covered	No
81402	Mopath procedure level 3	Covered	No
81406	Mopath procedure level 7	Covered	Yes
81408	Mopath procedure level 9	Covered	Yes
81410	Aortic dysfunction/dilation	Covered	Yes
81411	Aortic dysfunction/dilation	Covered	Yes
81412	Ashkenazi jewish assoc dis	Covered	Yes
81413	Car ion chnnlpath inc 10 gns	Covered	Yes
81414	Car ion chnnlpath inc 2 gns	Covered	Yes
81415	Exome sequence analysis	Covered	Yes
81416	Exome sequence analysis	Covered	Yes
81417	Exome re-evaluation	Covered	Yes
81425	Genome sequence analysis	Covered	Yes
81426	Genome sequence analysis	Covered	Yes
81427	Genome re-evaluation	Covered	Yes
81430	Hearing loss sequence analys	Covered	Yes
81431	Hearing loss dup/del analys	Covered	Yes
81432	Hrdtry brst ca-rlatd dsords	Covered	Yes
81433	Hrdtry brst ca-rlatd dsords	Covered	Yes
81434	Hereditary retinal disorders	Covered	Yes
81435	Hereditary colon ca dsords	Covered	Yes
81436	Hereditary colon ca dsords	Covered	Yes
81437	Heredtry nurondcrn tum dsrdr	Covered	Yes
81438	Heredtry nurondcrn tum dsrdr	Covered	Yes
81441	lbfms seq alys pnl 30 genes	Covered	Yes
81442	Noonan spectrum disorders	Covered	Yes
81443	Genetic tstg severe inh cond	Covered	Yes

Table 1 – Newly covered biomarker testing codes, effective for DOS on or after July 1, 2024 (Continued)

Procedure code	Description	Program coverage	PA required
81445	Targeted genomic seq analys	Covered	Yes
81448	Hrdtry perph neurphy panel	Covered	Yes
81449	So neo gsap 5-50 rna alys	Covered	Yes
81451	Hl neo gsap 5-50 rna alys	Covered	Yes
81456	So/hl 51/>gsap rna alys	Covered	Yes
81460	Whole mitochondrial genome	Covered	Yes
81465	Whole mitochondrial genome	Covered	Yes
81517	Test for detecting 3 biomarkers associated with risk for liver disease	Covered	No
81518	Onc brst mrna 11 genes	Covered	Yes
81520	Onc breast mrna 58 genes	Covered	Yes
81521	Onc breast mrna 70 genes	Covered	Yes
81523	Onc brst mrna 70 cnt 31 gene	Covered	Yes
81539	Oncology (high-grade prostate cancer), biochemical assay of four proteins (total psa, free psa, intact psa, and human kallikrein-2 [hk2]), utilizing plasma or serum, prognostic algorithm reported as a probability score	Covered	Yes
81595	Cardiology hrt trnspl mrna	Covered	Yes
87523	Detection of Hepatitis D (delta)	Covered	No
0009U	Onc brst ca erbb2 amp/nonamp	Covered	No
0016U	Onc hmtlmf neo rna bcr/abl1	Covered	No
0017U	Onc hmtlmf neo jak2 mut dna	Covered	No
0027U	Jak2 gene trgt seq alys	Covered	No
0029U	Rx metab advrs trgt seq alys	Covered	Yes
0030U	Rx metab warf trgt seq alys	Covered	No
0034U	Tpmt nudt15 genes	Covered	Yes
0037U	Trgt gen seq dna 324 genes	Covered	Yes
0040U	Bcr/abl1 gene major bp quan	Covered	Yes
0045U	Onc brst dux carc is 12 gene	Covered	Yes
0070U	Cyp2d6 gen com&slct rar vrnt	Covered	Yes
0071U	Cyp2d6 full gene sequence	Covered	Yes
0072U	Cyp2d6 gen cyp2d6-2d7 hybrid	Covered	Yes
0073U	Cyp2d6 gen cyp2d7-2d6 hybrid	Covered	Yes

Table 1 – Newly covered biomarker testing codes, effective for DOS on or after July 1, 2024 (Continued)

Procedure code	Description	Program coverage	PA required
0074U	Cyp2d6 nonduplicated gene	Covered	Yes
0075U	Cyp2d6 5' gene dup/mlt	Covered	Yes
0076U	Cyp2d6 3' gene dup/mlt	Covered	Yes
0094U	Genome rapid sequence alys	Covered	Yes
0101U	Hered colon ca do 15 genes	Covered	Yes
0102U	Hered brst ca rlted do 17 gen	Covered	Yes
0103U	Hered ova ca pnl 24 genes	Covered	Yes
0111U	Oncology (colon cancer), trgt KRAS	Covered	Yes
0129U	Hereditary breast genomic seq	Covered	Yes
0130U	Hered colon ca do mrna pnl	Covered	Yes
0131U	Hereditary breast related disorder mrna	Covered	Yes
0132U	Hereditary ovarian related disorder mrna	Covered	Yes
0134U	Hereditary pan cancer disorder mrna	Covered	Yes
0135U	Hereditary gynecological cancer disorder mrna	Covered	Yes
0136U	ATM mrna seq	Covered	Yes
0137U	PALB2 mrna seq analysis	Covered	Yes
0138U	BRCA1, BRCA2 mrna seq analysis	Covered	Yes
0158U	Mlh1 mrna seq alys	Covered	Yes
0169U	Nudt15&tpmt gene com vrnt	Covered	Yes
0209U	Cytog const alys interrog	Covered	Yes
0212U	Rare ds gen dna alys proband	Covered	Yes
0213U	Rare ds gen dna alys ea comp	Covered	Yes
0214U	Rare ds xom dna alys proband	Covered	Yes
0215U	Rare ds xom dna alys ea comp	Covered	Yes
0216U	Neuro inh ataxia dna 12 com	Covered	Yes
0217U	Neuro inh ataxia dna 51 gene	Covered	Yes
0218U	Neuro musc dys dmd seq alys	Covered	Yes
0231U	Cacna1a full gene analysis	Covered	Yes
0233U	Fxn gene analysis	Covered	Yes
0235U	Pten full gene analysis	Covered	Yes

Table 1 – Newly covered biomarker testing codes, effective for DOS on or after July 1, 2024 (Continued)

Procedure code	Description	Program coverage	PA required
0236U	Smn1&smn2 full gene analysis	Covered	Yes
0237U	Car ion chnlpthy gen seq pnl	Covered	Yes
0238U	Onc Inch syn gen dna seq aly	Covered	Yes
0265U	Rar do whl gn&mtcdrl dna als	Covered	Yes
0267U	Rare do id opt gen mapg&seq	Covered	Yes
0327U	Ftl aneuploidy trsmy dna seq	Covered	Yes
0335U	Rare ds whl gen seq feta	Covered	Yes
0336U	Rare ds whl gen seq bld/slv	Covered	Yes
G9143	Warfarin respon genetic test	Covered	No

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